

**K223130 Shiley™ Pediatric Oral/Nasal Endotracheal Tube with TaperGuard™ Cuff, Non DEHP (86125, 86130, 86135, 86140, 86145, 86150, 86155, 86160)**

Aug 30, 2023  
331 days to decision

K223130 · Product code: **BTR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k223130/>

**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Tube, Tracheal (w/wo Connector) (BTR) |
| Date received         | Oct 3, 2022                           |
| Decision date         | Aug 30, 2023                          |
| Days to decision      | 331 days                              |
| Third-party review    | No                                    |
| Combination product   | No                                    |
| PCCP authorized       | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Covidien</b>                           |
| Location       | North Haven, CT, US                       |
| Contact        | Anila Tarte                               |
| 510(k) history | 130 submissions · 126 cleared · 2008-2024 |

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...